Bayer

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Pharmaceutical
Division

Biologicals Business Unit

Carol M. Moore
Vice President
Quality Assurance/Regulatory Affairs
Responsible Head/Agent

January 20, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. 99D-4577
(Draft) Guidance for Industry
Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma

Dear Sir/Madam

The purpose of this correspondence is to submit comments and suggestions on the Draft Guidance document entitled "Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma".

The comments and suggestions are presented in Appendix I immediately following this cover letter.

Please do not hesitate to contact me or Ms Jean Huxsoll at (510) 705-5117 if you have any questions regarding this correspondence.

Sincerely,

Carol M. Moore
Vice President
Quality Assurance and Regulatory Affairs
Responsible Head/Agent

CMM/BH

Attachment

99D-4577

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Comments/Suggestions on

Guidance for Industry (Draft)

Application of Current Statutory Authority to Nucleic Acid Testing of Pooled Plasma

General Comments:

As the document scope encompasses the testing of both blood and plasma, it is suggested that the title be changed to ".....Testing of Blood and Source Plasma" instead of ".....Testing of Pooled Plasma".

There appears to be some inconsistency with respect to the name of the material being tested; in some cases it is referred to as "blood" and in others it is referred to as "plasma". It is suggested that the term "blood and/or source plasma" always be used.

Section III. BACKGROUND

Re: Last paragraph – donor notification/counseling and product retrieval for positive units

It is implied that whenever any unit is determined to be positive by NAT, donor deferral, notification and counseling, plus product retrieval should occur. As this is not always required e.g., for Parvo B19, it is suggested that the relevant portions of the last paragraph be clarified/modified.

Section IV. REGULATORY CONCERNS

Re: Validation of relevant instruments and software and submission of a 510(k)

It is not clear as to whether or not a 510(k) is required for the computer software employed in nucleic acid testing. Can the validation be performed under the IND and submitted as part of BLA, thereby eliminating a 510(k)?

Section IV.B

Re: Four different regulatory approaches.

The use of four different approaches seems to make the regulatory requirements unnecessarily complicated. It is recommended that there be two sets of requirements/conditions. One would cover the manufacturer of the test/test kit, and the other would cover the user of the test/test kit.

A. The manufacturer would file an IND followed by a BLA (and perform tests on reference panels provided by FDA).

B. The user (who may either purchase test/test kit and perform testing in-house, or who may send samples for testing to the test/test kit manufacturer) would file license supplements for each plasma/blood product tested and provide details of the system used to manage the information generated by the testing.

A combined manufacturer and user (develops own test/test kit and uses it for its own products) would have to meet the requirements for both A and B.

Re: Reference panels of infectious agents provided by FDA to test/test kit manufacturers

It is recommended that the appropriate sections be reworded to clarify/confirm that it is the lot release of the tests/test kits that is dependent on the reference panel testing results (not the material produced from tested plasma).

In addition to the test/test kits ability to accurately identify the reference panel agents, is the sensitivity of test/test kits also to be evaluated? If so, it is recommended that FDA adopt international unit nomenclature so that detection limits between different laboratories can be accurately compared.

Following a review of the Section IV.B it seems that the reader would ask the following questions. It is therefore recommended that the answers be included in the final version of the guidance document.

- Would panel testing be done for every test/test kit lot?
- Assuming that panel testing is not performed for every lot, how often would panel testing be performed?
- How would a panel test failure impact tests/test kits manufactured?
- Could panel testing frequency be reduced after a specific number of successful tests?
- Would all test results have to submitted to CBER?
- Would manufacturers have to wait for CBER authorization to release lots?

The last sentence in last paragraph of Section B (fourth approach) states "Performance would be subject to lot-release testing by CBER" which implies CBER would perform the testing, whereas in three previous paragraphs it states/implies that the manufacturer would perform the testing using panels provided by CBER. It is suggested that the document be revised to clearly define who will do testing and monitoring.

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